

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SEPRACOR INC.,

Plaintiff,

v.

DEY, L.P. and DEY, INC.

Defendants.

C.A. No. 06-113-\*\*\* (MPT)  
C.A. No. 06-604-\*\*\* (MPT)  
(Consolidated)

**PLAINTIFF SEPRACOR INC.'S REPLY TO DEFENDANTS DEY, L.P. AND  
DEY, INC.'S THIRD AMENDED COUNTERCLAIMS**

Plaintiff Sepracor Inc. ("Sepracor") hereby responds to each of the numbered paragraphs of the Third Amended Counterclaims of Defendants Dey, L.P. and Dey, Inc. (collectively "Dey").<sup>1</sup> Sepracor expressly denies any allegations not admitted herein.

**REPLY TO THIRD AMENDED COUNTERCLAIMS**

**JURISDICTION AND VENUE**

42. Sepracor admits that Dey's Third Amended Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* The remaining allegations of paragraph 42 of Dey's Third Amended Counterclaims aver a legal conclusion and, as such, Sepracor is not required to admit or deny it.

43. Sepracor admits the allegations set forth in paragraph 43 of Dey's Third Amended Counterclaims.

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<sup>1</sup> Herein, Sepracor's numbered paragraphs track those of Dey's Third Amended Counterclaims which begin with paragraph number 42 and end with paragraph number 120.

44. Sepracor admits the allegations set forth in paragraph 44 of Dey's Third Amended Counterclaims.

45. Sepracor admits the allegations set forth in paragraph 45 of Dey's Third Amended Counterclaims.

### **THE PARTIES**

46. With regard to paragraph 46 of Dey's Third Amended Counterclaims, Sepracor admits that, in its Complaint for Patent Infringement, Sepracor claimed the following: Dey, L.P. is a limited partnership organized under the laws of Delaware, having its principal place of business at 2751 Napa Valley Corporate Drive, Napa, California; Dey, L.P.'s registered office in Delaware is located at 1209 Orange Street, Wilmington, Delaware, 19801; and Dey, L.P.'s registered agent for service of process in Delaware is the Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

47. With regard to paragraph 47 of Dey's Third Amended Counterclaims, Sepracor admits that, in its Complaint for Patent Infringement, Sepracor claimed the following: Dey, Inc. is a corporation organized under the laws of Delaware, having its principal place of business at 2751 Napa Valley Corporate Drive, Napa, California; Dey, Inc.'s registered office in Delaware is located at 1209 Orange Street, Wilmington, Delaware, 19801; and Dey, Inc.'s registered agent for service of process in Delaware is the Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

48. Sepracor admits the allegations set forth in paragraph 48 of Dey's Third Amended Counterclaims.

**PATENTS-IN-SUIT**

49. Sepracor admits the allegations set forth in paragraph 49 of Dey's Third Amended Counterclaims.

50. Sepracor admits the allegations set forth in paragraph 50 of Dey's Third Amended Counterclaims.

51. Sepracor admits the allegations set forth in paragraph 51 of Dey's Third Amended Counterclaims.

52. Sepracor admits the allegations set forth in paragraph 52 of Dey's Third Amended Counterclaims.

53. Sepracor admits the allegations set forth in paragraph 53 of Dey's Third Amended Counterclaims.

**ACTS GIVING RISE TO THE ACTION**

54. Sepracor admits the allegations set forth in paragraph 54 of Dey's Third Amended Counterclaims.

55. With regard to paragraph 55 of Dey's Third Amended Counterclaims, Sepracor admits that according to the Food and Drug Administration, Center for Drug Evaluation and Research, Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") listings, levalbuterol hydrochloride inhalation solutions, or methods of use, are claimed in U.S. Patent Nos. '755, '994, '090, '002, and '993.

56. Sepracor admits the allegations set forth in paragraph 56 of Dey's Third Amended Counterclaims.

57. Sepracor admits the allegations set forth in paragraph 57 of Dey's Third Amended Counterclaims.

58. Sepracor admits the allegations set forth in paragraph 58 of Dey's Third Amended Counterclaims.

59. Paragraph 59 of Dey's Third Amended Counterclaims avers a legal conclusion and, as such, Sepracor is not required to admit or deny it. Sepracor denies the allegation that Dey has not, does not, and will not infringe any valid and/or enforceable claim of the '755, '994, '090, '002, and '993 Patents.

#### **FIRST COUNTERCLAIM**

60. With regard to paragraph 60 of Dey's Third Amended Counterclaims, Sepracor restates and incorporates by reference its responses to each of the foregoing allegations as though fully set forth herein.

61. Paragraph 61 of Dey's Third Amended Counterclaims avers a legal conclusion and, as such, Sepracor is not required to admit or deny it. Sepracor denies the allegation that Dey does not infringe any claim of the '755, '994, '090, '002, and '993 Patents.

62. Sepracor denies the allegations set forth in paragraph 62 of Dey's Third Amended Counterclaims.

63. Sepracor denies the allegations set forth in paragraph 63 of Dey's Third Amended Counterclaims.

#### **SECOND COUNTERCLAIM**

64. With regard to paragraph 64 of Dey's Third Amended Counterclaims, Sepracor restates and incorporates by reference its responses to each of the foregoing allegations as though fully set forth herein.

65. Paragraph 65 of Dey's Third Amended Counterclaims avers a legal conclusion and, as such, Sepracor is not required to admit or deny it.

66. Sepracor denies the allegations set forth in paragraph 66 of Dey's Third Amended Counterclaims.

### **THIRD COUNTERCLAIM**

67. With regard to paragraph 67 of Dey's Third Amended Counterclaims, Sepracor restates and incorporates by reference its responses to each of the foregoing allegations as though fully set forth herein.

68. Sepracor admits that, on its face, the '755 patent indicates that it issued from U.S. Application No. 163,581, which is a continuation of U.S. Application No. 896,725, abandoned, which is a continuation of U.S. Application No. 461,262. Sepracor denies the remaining allegations set forth in paragraph 68 of Dey's Third Amended Counterclaims.

69. Sepracor admits the allegations set forth in paragraph 69 of Dey's Third Amended Counterclaims.

70. Sepracor admits the allegations set forth in paragraph 70 of Dey's Third Amended Counterclaims.

71. Sepracor admits the allegations set forth in paragraph 71 of Dey's Third Amended Counterclaims.

72. Sepracor admits the allegations set forth in paragraph 72 of Dey's Third Amended Counterclaims.

73. Sepracor admits that "Sepracor [is] the named assignee" for the '755, '994, '090, '002, and '993 patents. Sepracor also admits that the attorneys and/or agents who

prosecuted the '755, '994, '090, '002, and '993 patents were retained by Sepracor Inc. Sepracor denies the remaining allegations set forth in paragraph 73 of Dey's Third Amended Counterclaims.

74. Sepracor admits that United Kingdom/Great Britain Patent Specification 1,298,494 ("UK '494") indicates on its face: "Filed 17 June 1970[;]" "Complete Specification published 6 Dec. 1972[;]" and "Inventor DAVID MIDDLEMISS[.]" Sepracor also admits that page 1, column 1, lines 1-8, of UK '494 states that "ALLEN & HANBURYS LIMITED . . . do hereby . . . pray that a patent may be granted to us . . ." Sepracor admits that a copy of what is purported to be UK '494 is attached as Exhibit A to Dey's Third Amended Answer and Counterclaims. Sepracor admits that the Preliminary Amendment (document number 7) filed in U.S. Application No. 08/691,604 and dated May 7, 1997 states, on page 4, lines 2-4, that "[o]ne week before issue, on August 13, 1996, two references[, one reference being UK '494,] were brought to the attention of applicants' undersigned representative." Sepracor denies the remaining allegations set forth in paragraph 74 of Dey's Third Amended Counterclaims.

75. Sepracor denies the allegations set forth in paragraph 75 of Dey's Third Amended Counterclaims.

76. Sepracor admits that UK '494 states "[t]his invention is concerned with a process for the preparation of optical enantiomers of certain 1-phenyl-2-aminoethanol derivatives" in column 1, lines 9-12. Sepracor denies the remaining allegations set forth in paragraph 76 of Dey's Third Amended Counterclaims.

77. Sepracor admits that "[a]lbuterol (also known as salbutamol) is a 1-phenyl-2-aminoethanol derivative." Sepracor denies the remaining allegations set forth in paragraph 77 of Dey's Third Amended Counterclaims.

78. Sepracor denies the allegations set forth in paragraph 78 of Dey's Third Amended Counterclaims.

79. Sepracor admits that the Preliminary Amendment (document number 7) filed in U.S. Application No. 08/691,604 and dated May 7, 1997 states, on page 4, lines 7-8 and page 5, lines 1-3, that "applicants believe that the references are merely cumulative to the references already of record." Sepracor denies the remaining allegations set forth in paragraph 79 of Dey's Third Amended Counterclaims.

80. Sepracor denies the allegations set forth in paragraph 80 of Dey's Third Amended Counterclaims.

81. Sepracor denies the allegations set forth in paragraph 81 of Dey's Third Amended Counterclaims.

82. Sepracor denies the allegations set forth in paragraph 82 of Dey's Third Amended Counterclaims.

83. Sepracor admits that, through its registered United States patent agent, it cited UK '494 to the United States Patent and Trademark Office in a submission dated August 20, 1996, and UK '494, in column 1, lines 13-14 and 15-16, cites "United Kingdom Specification 1,200,886." Sepracor admits that United Kingdom/Great Britain Patent Specification 1,200,866 ("UK '866") indicates on its face: "Complete Specification published 5 Aug. 1970" and "Inventors LAWRENCE HENRY CHARLES LUNTS, PAUL TOON and DAVID TREVOR COLLIN[.]" Sepracor also admits that

page 1, lines 1-3, of UK '866 states that "ALLEN & HANBURYS LIMITED . . . do hereby . . . pray that a patent may be granted to us . . ." Sepracor admits that a copy of what is purported to be UK '866 is attached as Exhibit B to Dey's Third Amended Answer and Counterclaims. Sepracor denies the remaining allegations set forth in paragraph 83 of Dey's Third Amended Counterclaims.

84. Sepracor denies the allegations set forth in paragraph 84 of Dey's Third Amended Counterclaims.

85. Sepracor denies the allegations set forth in paragraph 85 of Dey's Third Amended Counterclaims.

86. Sepracor denies the allegations set forth in paragraph 86 of Dey's Third Amended Counterclaims.

87. Sepracor denies the allegations set forth in paragraph 87 of Dey's Third Amended Counterclaims.

88. Sepracor denies the allegations set forth in paragraph 88 of Dey's Third Amended Counterclaims.

89. Sepracor denies the allegations set forth in paragraph 89 of Dey's Third Amended Counterclaims.

90. Sepracor denies the allegations set forth in paragraph 90 of Dey's Third Amended Counterclaims.

91. Sepracor denies the allegations set forth in paragraph 91 of Dey's Third Amended Counterclaims.

92. Sepracor admits the allegations set forth in paragraph 92 of Dey's Third Amended Counterclaims.

93. Sepracor admits that the International Search Report for International Application No. PCT/US91/000088 cites EP-A-0248150, EP-A-0320550, and Trends Pharmacol. Sci., vol. 7/5, 1986, Elseviers Science Publishers B.V., (Amsterdam, NL), E.J. Ariëns: "Chirality in bioactive agents and its pitfalls," pages 200-205. Sepracor denies the remaining allegations set forth in paragraph 93 of Dey's Third Amended Counterclaims.

94. Sepracor admits that the International Search Report for International Application No. PCT/US91/000088 indicates on its face a date of mailing of "31.05.91." Sepracor denies the remaining allegations set forth in paragraph 94 of Dey's Third Amended Counterclaims.

95. Sepracor admits that the International Search Report for International Application No. PCT/US91/000088 indicates on its face that an "X" category document is considered in the International Search Report to be "a document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve inventive step." Sepracor denies the remaining allegations set forth in paragraph 95 of Dey's Third Amended Counterclaims.

96. Sepracor denies the allegations set forth in paragraph 96 of Dey's Third Amended Counterclaims.

97. Sepracor admits that paragraph 97 of Dey's Third Amended Counterclaims is a paraphrased excerpt from Section 2001.06(a) of The Manual of Patent Examining Procedure, Eighth Edition, Revision 3 (Aug. 2005).

98. Sepracor denies the allegations set forth in paragraph 98 of Dey's Third Amended Counterclaims.

99. Sepracor denies the allegations set forth in paragraph 99 of Dey's Third Amended Counterclaims.

100. Sepracor denies the allegations set forth in paragraph 100 of Dey's Third Amended Counterclaims.

101. With regard to paragraph 101 of Dey's Third Amended Counterclaims, Sepracor admits that SEP 0048306-17 includes a page stating "Sepracor Inc.," "*In Vitro* Testing of Salbutamol and its Optically Active Isomers in Guinea Pig Airways," "Sepracor Document No. 051-400," "Prof. Rolf G.G. Andersson," "Department of Pharmacology," "University Hospital Linoping, Sweden," and "19 October, 1993." Sepracor denies the remaining allegations set forth in paragraph 101 of Dey's Third Amended Counterclaims.

102. With regard to paragraph 102 of Dey's Third Amended Counterclaims, Sepracor admits that SEP 0048308 states, in part, that "[t]he dose-dependent relaxant effects of (R)-, (S)- and racemic albuterol were studied in isolated guinea pig tracheal rings contracted with carbachol ( $10^{-8}$  -  $10^{-6}$  M) or histamine ( $10^{-8}$  -  $10^{-5}$  M). . . . In addition, the relaxant effect of the beta agonists were evaluated in antigen-contracted tracheal preparations isolated from animals sensitized to egg-albumin." Sepracor denies the remaining allegations set forth in paragraph 102 of Dey's Third Amended Counterclaims.

103. Sepracor denies the allegations set forth in paragraph 103 of Dey's Third Amended Counterclaims.

104. Sepracor denies the allegations set forth in paragraph 104 of Dey's Third Amended Counterclaims.

105. Sepracor denies the allegations set forth in paragraph 105 of Dey's Third Amended Counterclaims.

106. Sepracor admits that SEP 0048306-17 was produced from Sepracor's files relating to NDA 20-837. Sepracor denies the remaining allegations set forth in paragraph 106 of Dey's Third Amended Counterclaims.

107. Sepracor denies the allegations set forth in paragraph 107 of Dey's Third Amended Counterclaims.

108. Sepracor denies the allegations set forth in paragraph 108 of Dey's Third Amended Counterclaims.

109. Sepracor denies the allegations set forth in paragraph 109 of Dey's Third Amended Counterclaims.

110. Sepracor denies the allegations set forth in paragraph 110 of Dey's Third Amended Counterclaims.

111. Sepracor admits that DLEV012293 states, in part, "[m]oreover, it is the Examiner's opinion that it would not have been expected from the prior art of record that the R(-) isomer of albuterol would possess the improved side effect profile as established in the declaration of Dr. Aberg filed July 23, 1993, i.e., that the R(-) isomer of albuterol does not cause the hypersensitivity reaction normally associated with long-term racemic albuterol administration in patients suffering from asthma. This fact is highly significant and compels the Examiner to conclude that the presently claimed invention would not have been obvious under 35 U.S.C. § 103." Sepracor denies the remaining allegations set forth in paragraph 111 of Dey's Third Amended Counterclaims.

112. Sepracor admits the allegations to the extent that it admits the declarants were aware of at least the information contained in their respective declarations. Sepracor denies the remaining allegations set forth in paragraph 112 of Dey's Third Amended Counterclaims.

113. Sepracor denies the remaining allegations set forth in paragraph 113 of Dey's Third Amended Counterclaims.

114. Sepracor denies the allegations set forth in paragraph 114 of Dey's Third Amended Counterclaims.

115. Sepracor denies the allegations set forth in paragraph 115 of Dey's Third Amended Counterclaims.

116. Sepracor denies the allegations set forth in paragraph 116 of Dey's Third Amended Counterclaims.

117. Paragraph 117 of Dey's Third Amended Counterclaims avers a legal conclusion and, as such, Sepracor is not required to admit or deny it. Sepracor denies the allegation that the '755, '994, '090, '002, and '993 patents are unenforceable.

118. Sepracor denies the allegations set forth in paragraph 118 of Dey's Third Amended Counterclaims.

#### **FOURTH COUNTERCLAIM**

119. With regard to paragraph 119 of Dey's Third Amended Counterclaims, Sepracor restates and incorporates by reference its responses to each of the foregoing allegations as though fully set forth herein.

120. Sepracor denies the allegations set forth in paragraph 120 of Dey's Third Amended Counterclaims.

**DEFENSES**

**FIRST DEFENSE**

Dey's Third Amended Counterclaims fail to state a claim upon which relief can be granted.

**SECOND DEFENSE**

The making, using, selling, offering to sell, or importing of Dey's Levalbuterol Inhalation Solutions does and will, if marketed, infringe one or more claims of each of the '755, '994, '090, '002, and '993 Patents (the "Sepracor Patents").

**THIRD DEFENSE**

The making, using, selling, offering to sell, or importing of Dey's Levalbuterol Inhalation Solution Concentrate does and will, if marketed, infringe one or more claims of each of the Sepracor Patents.

**FOURTH DEFENSE**

The claims of the Sepracor Patents are valid under all conditions of patentability set forth in Title 35 of the United States Code.

**FIFTH DEFENSE**

The claims of the Sepracor Patents are enforceable.

**PRAYER FOR RELIEF**

WHEREFORE, Sepracor denies that Dey is entitled to any of the relief requested in Dey's Prayer for Relief and respectfully requests that the Third Amended Counterclaims of Dey be dismissed with prejudice; and that judgment be entered in favor of Sepracor as follows:

(A) A judgment declaring that Dey has infringed and that Dey's making, using, selling, offering to sell and/or importing of Dey's Levalbuterol Inhalation Solutions will infringe one or more claims of each of the Sepracor Patents;

(B) A judgment declaring that the effective date of any approval of Dey's ANDA No. 77-800 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for Dey's Levalbuterol Inhalation Solutions must be no earlier than the expiration date of the last to expire of the infringed Sepracor Patents.

(C) A permanent injunction enjoining Dey, its officers, agents, attorneys, and employees, and anyone acting in concert with them, from making, using, selling, offering to sell, and/or importing Dey's Levalbuterol Inhalation Solutions until after the expiration of the last to expire of the infringed Sepracor Patents.

(D) A judgment declaring that Dey has infringed and that Dey's making, using, selling, offering to sell and/or importing of Dey's Levalbuterol Inhalation Solution Concentrate will infringe one or more claims of each of the Sepracor Patents;

(E) A judgment declaring that the effective date of any approval of Dey's ANDA No. 78-309 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for Dey's Levalbuterol Inhalation Solution Concentrate must be no earlier than the expiration date of the last to expire of the infringed Sepracor Patents.

(F) A permanent injunction enjoining Dey, its officers, agents, attorneys, and employees, and anyone acting in concert with them, from making, using, selling, offering to sell, and/or importing Dey's Levalbuterol Inhalation Solution Concentrate until after the expiration of the last to expire of the infringed Sepracor Patents.

(G) A judgment that Dey's infringement of the Sepracor Patents was and is willful, and that Sepracor is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

(H) A judgment awarding Sepracor costs and expenses in this action.

(I) Such other and further relief as the Court deems just and equitable.

September 27, 2007

THE BAYARD FIRM

/s/ Richard D. Kirk (rk0922)

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**CERTIFICATE OF SERVICE**

The undersigned counsel certifies that, on September 27, 2007, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

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The undersigned counsel further certifies that, on September 27, 2007 copies of the foregoing document were sent by email and hand to the above local counsel and by email and first class mail to the following non-registered participants:

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Richard D. Kirk

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